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10/538,423

01/30/2006

Arunendra Nath Lahiri Majumder

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THE WEBB LAW FIRM, P.C.  
700 KOPPERS BUILDING  
436 SEVENTH AVENUE  
PITTSBURGH, PA 15219

EXAMINER

PROUTY, REBECCA E

ART UNIT

PAPER NUMBER

1652

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/538,423	<b>Applicant(s)</b> MAJUMDER ET AL.	
	<b>Examiner</b> Rebecca E. Prouty	<b>Art Unit</b> 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

The listing of references in the Search Report is not considered to be an information disclosure statement (IDS) complying with 37 CFR 1.98. 37 CFR 1.98(a)(2) requires a legible copy of: (1) each foreign patent; (2) each publication or that portion which caused it to be listed; (3) for each cited pending U.S. application, the application specification including claims, and any drawing of the application, or that portion of the application which caused it to be listed including any claims directed to that portion, unless the cited pending U.S. application is stored in the Image File Wrapper (IFW) system; and (4) all other information, or that portion which caused it to be listed. In addition, each IDS must include a list of all patents, publications, applications, or other information submitted for consideration by the Office (see 37 CFR 1.98(a)(1) and (b)), and MPEP § 609.04(a), subsection I. states, "the list ... must be submitted on a separate paper." Therefore, the references cited in the Search Report have not been considered. Applicant is advised that the date of submission of any item of information or any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the IDS, including all "statement" requirements of 37 CFR 1.97(e). See MPEP § 609.05(a).

Applicant is required to comply with the sequence rules by inserting the sequence identification numbers of all sequences recited in the specification and claims. It is particularly noted that claim 1 and pages 5-7 of the specification include sequences without any sequence identification numbers and Figure 1 includes sequences without any sequence identification numbers recited in the figure or brief description thereof. See particularly 37 CFR 1.821(d).

The disclosure is objected to because of the following informalities: There is not a section of the specification titled Brief Description of the Drawings.

Appropriate correction is required.

The abstract of the disclosure is objected to because the abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The Figure recited in the abstract should be replaced with the corresponding sequence identifiers in order to limit the space required. Correction is required. See MPEP § 608.01(b).

The disclosure is objected to because of the following informalities: the amino acid and nucleotide sequences of the

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*Porteresia coarctata* myo-inositol 1-phosphate synthase recited on page 5-6 of the specification and in Figure 1 do not agree with each other. It is noted that nucleotides 67-69 of the nucleotide sequence are GAG which are shown as encoding a tryptophan (W) residue and residues 124-126 are TGG which are shown as encoding a histidine (H) residue. However, GAG is a codon for glutamic acid (E) not tryptophan and TGG is a codon for tryptophan (W) and not histidine. Thus it is not clear what the correct sequences are. Applicants should note that the sequences have not been completely checked for other errors in agreement and thus others may be present as well. The two recited instances are merely discrepancies which have been noticed by the examiner in the course of examination. Appropriate correction is required.

The sequence listing filed 1/30/06 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: SEQ ID NOS: 1 and 3 of the sequence listing recite sequences not found within the specification as filed as they differ in several positions from the sequences recited in pages 5-6 of the specification and in Figure 1. It is noted

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that nucleotides 34-36 of SEQ ID NO:1 differ from the nucleotide sequence reported on pages 5-6 and in Figure 1 of the specification as filed is the sequence originally filed recites the sequence CAC at these positions while SEQ ID NO:1 recites CGC at these positions. It is noted that amino acid residues 42, 69, 346, and 378 of SEQ ID NO:3 differ from the amino acid sequence reported on pages 5-6 and in Figure 1 of the specification as filed is the sequence originally filed recites the residues H, W, T, and P at these positions while SEQ ID NO:3 recites the residues Y, Y, M, and L at these positions

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim 3 is objected to because of the following informalities: the genus and species names recited should be underlined or italicized. Appropriate correction is required.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 2 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

In the absence of the hand of man, naturally occurring DNAs are considered non-statutory subject matter. Diamond v. Chakrabarty, 206 USPQ 193 (1980). This rejection may be overcome

by amending the claims to contain wording such as "An isolated and purified DNA ...".

Claims 1-2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is confusing in the recitation of a myo-inositol 1-phosphate synthase from *Porteresia coarctata* (PIN01) the nucleotide sequences and the deduced amino acid sequence as given below as proteins do not have nucleotide sequences. Thus it is unclear if the claim is intended to recite a protein or a nucleic acid. Furthermore, the claim is confusing in that the recited nucleotide sequence does not encode the recited amino acid sequence as described in the objection to the disclosure above. It is presumed that the claim recites a protein encoded by the recited nucleotide sequence.

Claim 2 is confusing in the recitation of "The DNA sequence coding as claimed in claim 1" as claim 1 recites a protein not a DNA sequence. Furthermore, it is confusing if this claim is limited to a DNA comprising the nucleotide sequence recited in claim 1 or if it is intended to include any nucleic acid encoding the protein of claim 1.

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Claim 2 is confusing in the recitation of "further codes for two additional amino acids resulting in a protein bearing 512 amino acids" as the nucleotide sequence recited in claim 1 encodes a protein of 512 amino acids. Thus the meaning of "further codes" is confusing and unclear.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Raychaudhuri et al.

Raychaudhuri et al. teach the isolation of *Porteresia coarctata* myo-inositol 1-phosphate synthase. Although Raychaudhuri et al. do not recite the amino acid sequence of the isolated protein the amino acid sequence recited in the claim is an inherent property of the protein disclosed by the reference.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner



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presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raychaudhuri et al. in view of Yoshida et al.

Raychaudhuri et al. teach the isolation of the salt tolerant *Porteresia coarctata* myo-inositol 1-phosphate synthase but do not teach methods of isolating and expressing the cDNA encoding this protein

Yoshida et al. teach methods of isolating the cDNA encoding the *Oryza sativa* myo-inositol 1-phosphate synthase comprising reverse transcribing mRNA from the rice plant and PCR amplification followed by insertion of the full length cDNA into a suitable vector.

Therefore, it would have been obvious to one of ordinary skill in the art to isolate the cDNA of the myo-inositol 1-phosphate synthase of Raychaudhuri et al. using the methods of Yoshida et al. and to further express the encoded protein. One of ordinary skill in the art would have been motivated to do so as the many advantages of recombinant production of useful proteins are well known within the art as are recombinant methods of expressing the genes. These advantages include the

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ability to produce much larger quantities of the protein, being able to produce the protein in more easily handled organisms, reducing the number of steps necessary for the purification of a protein and producing the protein in a purer form by using an organism that does not include naturally occurring contaminants of the protein. Furthermore, while Yoshida et al. do not teach the use of the pET20B(+) vector, and *E. coli* BL-21 (DE 3) host recited in claims 4 and 5, these are a well known commercially available expression vector and host cell and thus it would have been obvious to one of skill in the art to select these as a suitable vector and host cell. Furthermore, while the references do not recite the specific solubilization buffer of claim 6, this buffer differs from that disclosed by Raychaudhuri et al. for the isolation of the *Porteresia coarctata* myo-inositol 1-phosphate synthase only in the inclusion of 8M urea. It is well known in the art that proteins expressed in *E. coli* often are produced as inclusion bodies which need to be resolubilized and that buffers suitable for the enzyme which include 8M urea are generally useful for doing so. Therefore, it would have been obvious to use this buffer for the resolubilization of the protein following expression.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca E. Prouty whose telephone number is 571-272-0937. The examiner

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can normally be reached on Tuesday-Friday from 8 AM to 5 PM.  
The examiner can also be reached on alternate Mondays

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed, can be reached at (571) 272-0934. The fax phone number for this Group is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rebecca Prouty/  
Primary Examiner  
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